

## General

### Guideline Title

Quality improvement guidelines for percutaneous management of acute lower-extremity ischemia.

### Bibliographic Source(s)

Patel NH, Krishnamurthy VN, Kim S, Saad WE, Ganguli S, Walker TG, Nikolic B, CIRSE and SIR Standards of Practice Committees. Quality improvement guidelines for percutaneous management of acute lower-extremity ischemia. J Vasc Interv Radiol. 2013 Jan;24(1):3-15. [119 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Rajan DK, Patel NH, Valji K, Cardella JF, Brown DB, Brountzos EN, Clark TW, Grassi CJ, Meranze SG, Miller DL, Neithamer CD, Rholl K, Roberts A, Schwartzberg MS, Swan TT, Thorpe PE, Towbin RB, Sacks D, CIRSE and SIR Standards of Practice Committees. Quality improvement guidelines for percutaneous management of acute limb ischemia. J Vasc Interv Radiol. 2009 Jul;20(7 Suppl):S208-18. [91 references]

## Recommendations

### Major Recommendations

#### Indications/Patient Selection

Patient selection is determined by a number of clinical findings of the limb in question (see Tables 4 and 5 in the original guideline document). Patients can usually relate their deterioration of symptoms to a particular time period. An appropriate history and physical examination and an evaluation of the patient for absolute and relative contraindications to thrombolytic therapy should be performed. The history should focus on when, where, and what events surrounded the acute limb ischemia (ALI) symptoms. The patient should be evaluated for pain, sensory deficit, numbness, paresthesia, decreased motor function, pallor, and decreased temperature. Laboratory tests should be obtained to assess for renal function, baseline hematocrit and coagulation profile, and evidence of hyperkalemia and acidosis. An electrocardiogram may be obtained to ascertain if any cardiac arrhythmias are present and to assess for a recent myocardial infarction. Doppler examination of the limb should be obtained when possible.

If possible, it is also important to try to determine the etiology of ALI, whether it is embolic or thrombotic (see Table 6 in the original guideline document). This will affect immediate and long-term management. In an embolic event, the heart is the source in 80% to 90% of cases with a majority of these having underlying myocardial disease. Arrhythmias, such as atrial fibrillation, can have a 3% to 6% annual risk of thromboembolic complications if they are not treated with anticoagulation. In cases of an embolic event, the symptoms are often of sudden onset and severe, and

these patients may be better served with embolectomy, which can often be performed with local anesthesia. In thrombotic events, the patients often have more gradual onset, and may have a collateral network of arteries and less severe symptoms, all of which may provide enough of a time window to undertake treatment with percutaneous intervention. In cases of embolism, an attempt must be made to discover the source, whether it be a paradoxical embolus, cardiogenic, or valvular, or from a proximal arteriogenic source such as an aneurysm or atherosclerotic plaque. The source of emboli must also be addressed to reduce the likelihood of future embolic events. Doppler imaging examination of the limb should be performed when possible.

Patients with ALI are considered candidates for thrombolysis when they present with Rutherford category 1 or IIa ischemia, and an algorithmic approach has been proposed (see figure in the original guideline document). Patients with category IIb ischemia may be candidates for thrombolysis, but the method of clot removal must be expeditious. Mechanical devices may reduce the time to restoration of flow, thereby allowing patients with more severe degrees of ischemia to undergo percutaneous thrombolysis. The treating physician must make this determination on a case-by-case basis. Patients with category III ischemia should not be treated percutaneously because catheter-based thrombolytic therapy often takes many hours and ischemic changes may become irreversible over the course of treatment. In addition, revascularization of category III ischemia carries the added risk of toxic shock syndrome.

Intravenous heparin at full anticoagulation doses should be initiated as soon as possible and continued until thrombolysis is started. Prompt initiation of anticoagulation reduces or prevents clot propagation and reduces the chances of further embolization. In one study, the time from establishing diagnosis to initiation of therapy was correlated with amputation rates. The amputation rates were 6% if thrombolytic therapy was initiated within 12 hours of development of acute symptoms of ischemia, 12% if initiated within 13 to 24 hours, and 20% if initiated after 24 hours. It is very important to control pain and treat any underlying medical condition such as congestive heart failure and cardiac arrhythmias.

Important questions to consider before undertaking therapy include whether (i) the patient can tolerate the anticipated time of treatment, (ii) the total clot burden is suitable for thrombolysis in a reasonable length of time, (iii) the clot location is within reach of the thrombolytic catheters/devices, and (iv) the patient has risks of thrombolysis/anticoagulation that outweigh the benefits of the thrombolytic therapy.

Published studies indicate that patients with acute leg ischemia of less than 14 days duration and those with acute bypass graft occlusions benefit most from thrombolysis; the benefits reported were improved survival and improved long-term patency of the limb when thrombolysis was the initial therapeutic option. Subanalysis of the data showed that lower amputation and mortality rates occurred when patients were randomized to undergo thrombolysis versus surgery when symptoms were less than 14 days in duration, whereas a higher rate was seen in patients with symptoms for greater than 14 days. Further analysis of the STILE trial indicated that 1-year amputation-free survival rate was significantly higher in patients with ALI randomized to receive thrombolytic therapy compared with surgery (20% vs 48% [ $P = .026$ ]; failure of catheter placement occurred in 28% of patients). In a study in which patients were randomized between surgery and thrombolytic therapy, after 12 months, 84% of the patients randomized to receive thrombolytic therapy were alive, whereas only 58% of those randomized to surgery were still alive ( $P = .01$ ). Further subgroup analysis of the STILE data in two reports suggests that thrombolysis appears to be more effective for graft occlusions than for native artery occlusions. Based on the results of the TOPAS and STILE trials, a working group proposed that thrombolytic therapy should be considered appropriate initial management in patients with acute occlusion of the leg arteries or bypass grafts. These recommendations are not absolute, as they are based on subgroup analysis of patient populations within larger trials. Some studies have also indicated that the likelihood of limb salvage after thrombolytic therapy is greater when a greater number of patent vessels are present.

Contraindications to pharmacologic thrombolytic therapy (see the "Contraindications" field) are based on medical conditions thought to increase the risk of local and remote hemorrhage. The recommendations were arrived at by consensus and are not evidence-based. It may be that risks of remote or systemic hemorrhage are lower with catheter-directed thrombolysis, which uses lower doses of drug compared with systemic doses, albeit over longer periods of time. Therefore, the listed contraindications should be used to weigh the relative risks and benefits of thrombolytic treatment in patients who may have conditions that also increase the risk of the requirement of surgical therapy. Patients with relative contraindications may be appropriate to treat with thrombolysis. When clinically significant bleeding is recognized, continuation of thrombolytic therapy is dependent on the clinical status of the patient and the severity of bleeding. Attempts should be made to identify the site of bleeding and treat the cause appropriately. Contraindications that may exist for catheter-based angiography should also be considered.

Current endovascular therapies employed to treat ALI involve administration of thrombolytic agents through an infusion catheter placed in the thrombus (i.e., pharmacologic thrombolysis), mechanical disruption/fragmentation combined with/without aspiration of debris (i.e., mechanical thromboembolectomy) or a combination of the techniques (i.e., pharmacomechanical thrombolysis). The indication for percutaneous management of ALI is presentation with acute symptoms with Rutherford category 1 or 2 ischemia determined by physical and Doppler examination (see Table 5 in the original guideline document).

Removal of the clot not only restores antegrade blood flow to the distal ischemic limb, but, moreover, it unmasks the underlying causative lesion. Correction of this lesion, whether by endovascular or surgical means, is paramount to good outcome.

## Thrombolytic Therapy

### Thrombolytic Agents

All clinically available thrombolytic agents are plasminogen activators, and do not directly degrade fibrinogen. They all activate plasminogen, thereby converting plasminogen to plasmin. The plasmin then breaks down the fibrin and fibrinogen contained in the clot into fibrinogen degradation products. All currently available agents have varying degrees of fibrin specificity, the ability to distinguish between circulating and bound plasminogen (see Table 2 in the original guideline document). Streptokinase (SK) and urokinase (UK) are non-fibrin-specific plasminogen activators. Tissue plasminogen activators (tPAs) are fibrin-specific agents that preferentially activate fibrin-bound (i.e., clot-bound) plasminogen. Their higher fibrin specificity was hoped to lower systemic bleeding complications; however, large trials have shown no significant difference in bleeding rates.

Refer to the original guideline document for descriptions of how different thrombolytic agents are produced, their mechanism of action, and thrombolytic efficacy in clinical trials.

### Dosage

#### *Urokinase*

The most commonly described protocol for UK is a graded infusion regimen consisting of 240,000 U/h for 4 hours, then a lower dosage of 120,000 U/h for a maximum infusion time of 48 hours. The TOPAS phase I study appears to show that the dosage of UK associated with the lowest risk of hemorrhage (2%) that maximized thrombolytic efficacy (71%) was 4,000 U/min. No significant differences among dosages and surgery in terms of mortality and amputation were found in this study. In another study, a comparison was made between high-dose and low-dose UK infusions for native arterial and graft occlusions. The high-dose UK regimen was 250,000 U/h for 4 hours, then 125,000 U/h. The low-dose UK regimen was 50,000 U/h. This small study suggested that both dose regimens were equally effective but there was a higher frequency of minor bleeding complications in the high-dose group.

#### *Tissue Plasminogen Activators*

Alteplase (TPA) weight-adjusted doses have ranged from 0.02 to 0.1 mg/kg/h, whereas non-weight-based doses generally range from 0.25 to 1.0 mg/h, even though higher doses have been reported. In general, the lowest effective dose has not been determined. One multicenter study randomized 100 patients with acute leg ischemia of less than 30 days duration. This study compared high-dose TPA (3–5-mg bolus doses, then 3.5 mg/h for a maximum of 4 h, then 0.5–1.0 mg/h) versus low-dose TPA (0.5–1.0 mg/h). There were no statistically significant differences between the two groups in terms of 30-day limb salvage or complication rates. An advisory panel was convened in 1999 to provide guidelines for the use of alteplase. The suggested dosage regimens were (i) a weight-adjusted dose of 0.001–0.02 mg/kg/h and (ii) a non-weight-adjusted dose of 0.12–2.0 mg/h. No formal recommendation was made regarding the use of weight-adjusted versus non-weight-adjusted dosing. The recommended maximum dosing was no greater than 40 mg for catheter-directed therapy.

For reteplase (RPA), a consensus document published in 2001 suggested that the minimum dose should not be less than 0.25 U/h, with a dose range of 0.25–1.0 U/h. Maximum dose amount and infusion time suggested were 20 U and 24 hours, respectively. In a study examining different doses of reteplase for lower-extremity arterial occlusions, doses of 0.5 U/h, 0.25 U/h, and 0.125 U/h were found to be equally effective, with more bleeding complications with the highest dose.

### Delivery Methods

Intravenous administration of thrombolytic agents should not be performed for ALI. A randomized parallel-group study showed that intravenous administration of TPA led to a higher rate of hemorrhagic complications with less successful thrombolysis than intraarterial delivery.

Treatment is usually initiated when the occluded segment is successfully traversed with a guide wire (i.e., guide wire traversal test). Attempts to pass a guide wire through the acute thrombus to initiate thrombolysis should be made. If a wire cannot be passed, a short period of thrombolysis may be initiated. If a wire cannot be passed after this short period of time, consideration should be given to other methods of revascularization.

Multiple techniques for intrathrombus infusion of thrombolytic agents have been described, including (i) intrathrombus bolus administration followed by continuous low-dose intrathrombus infusion with use of an infusion wire or catheter with multiple side holes for maximum surface area exposure; (ii) stepwise and graded intrathrombus infusion; and (iii) pulse-spray pharmacomechanical thrombolysis. Intrathrombus infusion represents the current state of practice, with placement of an infusion wire or multiple-side hole delivery catheter completely along the length of the thrombus, as this is associated with a greater chance of complete thrombolysis.

Intrathrombus bolus administration of TPA appears to reduce the duration of treatment and may be of advantage in acutely ischemic limbs, but

with increased risk of hemorrhage compared with lower-dose continuous infusion.

Although intraoperative thrombolysis may have a role at the time of operative revascularization to dissolve clot in the distal vasculature, sufficient data are not available to allow an opinion regarding efficacy and outcome to be rendered.

Ultrasound (US)-enhanced thrombolysis is one of the newest ideas in thrombolysis, which uses sound waves to accelerate thrombolysis. Low-frequency US mechanically fragments clots and augments. Several devices have been developed to try to increase the efficacy of clot dissolution by using these principles, and the Ekosonic Mach-4e device (Ekos, Bothell, Washington) is currently commercially available. In addition to drug delivery, the Ekosonic device delivers sound waves into the clot in the aim to accelerate the speed and improve the completeness of thrombolysis.

The delivery method or device that provides optimal thrombolysis has not been studied in large prospective trials.

#### Heparin Use during Thrombolytic Infusions

The published literature shows varying doses used in thrombolytic infusion, from none to therapeutic anticoagulation, with no dose identified that predicts adverse bleeding. Heparin should be used carefully during thrombolytic infusions because of the risk of bleeding. Generally, subtherapeutic doses of heparin are acceptable when used in combination with thrombolytic therapy, although therapeutic doses are recommended with UK infusion treatment. In the study, pericatheter thrombosis occurred in two of seven infusions when heparin was not administered concurrently. In another study, therapeutic doses of heparin initially administered intravenously were associated with an intracranial hemorrhage rate of 4.8%. The protocol in this study was subsequently revised by reducing the heparin dose to prevent pericatheter thrombosis to a subtherapeutic dose and administering it through the arterial sheath instead of intravenously.

With fibrinogenolysis, the products of fibrinogen degradation increase the patient's sensitivity to heparin, possibly making the patient more prone to bleeding. Careful monitoring of partial thromboplastin time is recommended. Postthrombolysis anticoagulation is recommended until the underlying lesion, if any, is corrected.

#### Laboratory Monitoring

No clinical trials have been completed to support laboratory monitoring that may predict adverse bleeding during thrombolytic therapy. Although monitoring of serum fibrinogen levels is thought by some to predict adverse bleeding, no pivotal study has validated this belief. In the Prourokinase versus Recanalization of Peripheral Occlusions, Safety and Efficacy trial, 13 of 16 patients (81.3%) with a serum fibrinogen level of less than 100 mg/dL had a major or minor bleeding complication, compared with 105 of 179 patients (58.7%) with serum fibrinogen levels greater than 100 mg/dL ( $P = .108$ ). In the STILE trial, it was demonstrated that patients with bleeding complications had a significantly lower plasma fibrinogen level at the end of infusion ( $P = .01$ ). Another study demonstrated that major complications were associated with a mean 72% decrease in fibrinogen level, whereas minor complications were associated with a mean 46% decrease in fibrinogen level. Routine monitoring of hemoglobin may allow for detection of significant occult bleeding before it becomes clinically apparent.

The tPAs (TPA, RPA, and, to a lesser extent, tenecteplase [TNK]) generate fragment X, a high molecular weight fibrinogen degradation product. When fragment X is incorporated into the clot, the clot becomes more susceptible to lysis. However, fragment X also becomes incorporated into hemostatic plugs, making them more easily lysed and thereby increasing the potential for bleeding. In contrast to tPAs, UK and SK, which are not fibrin-specific, do not generate fragment X. Instead, they generate much smaller fibrinogen degradation products (fragments Y, D, and E) that are neither clottable nor incorporated into the hemostatic plug.

#### Adjunctive Techniques

The complexity of the underlying causative lesion that is unmasked through thrombolytic therapy predicts the long-term patency and limb salvage rates.

When flow in the vessel has been restored, repeat angiography should be performed to define the vascular anatomy and areas of disease that may require additional treatment. In most cases, a causative lesion will be identified, and this should be managed with the appropriate endovascular technique or conventional surgical procedure. Failure to detect and rectify an underlying lesion is associated with poor long-term patency.

The speed and long-term efficacy of intraarterial thrombolysis can be enhanced by using adjunctive techniques. These techniques will help achieve two clinically important endpoints:

1. They may be used in conjunction with thrombolysis to remove insoluble material, or debulk the thrombus to accelerate the restoration of flow; and
2. They may be used to correct underlying lesions at the time of thrombolysis or in the periprocedural period.

Among the procedures that may be used in conjunction with or independent of pharmacologic thrombolysis are percutaneous aspiration

thromboembolectomy (PAT) and the use of mechanical thromboembolectomy devices (MTDs). In patients in whom it is important to accelerate thrombolysis or remove residual clot, PAT and MTD use are alternatives.

### Percutaneous Aspiration Thromboembolectomy

The PAT technique uses a large-bore catheter connected to a syringe to aspirate (i.e., suction) clot from vessels. This technique can be used alone or in conjunction with thrombolytic therapy. PAT is typically used as an adjunct to thrombolysis in acute arterial occlusion, or can be used as salvage therapy to remove distal emboli. Low-profile, dual-lumen, rapid-exchange aspiration thrombectomy catheters are also commercially available, such as the Pronto extraction catheter (Vascular Solutions, Minneapolis, Minnesota), Export catheter (Medtronic, Minneapolis, Minnesota), Xpress-Way extraction catheter (Atrium Medical), ASAP catheter (Merit Medical, South Jordan, Utah), and Fetch catheter (Medrad). The efficacy and volume of clot extracted with these catheters are not equivalent to those extracted with the use of MTDs. However, the apparent benefits of these catheters are their atraumatic distal tips, minimal risk of distal embolization, ability to intervene within smaller-caliber arteries, and no evidence of hemolysis. Data on ALI with these devices are very limited, and there are no comparative data between PAT catheters and MTDs.

### Percutaneous Mechanical Thromboembolectomy Device

As many as 20% of patients can have a contraindication to thrombolytic therapy. MTDs are particularly useful in such patients with contraindications to thrombolytic therapy. In patients at higher risk for bleeding, MTDs can be used to debulk the thrombus mass before local lysis to shorten the lytic treatment period, thereby limiting the dose of thrombolytic agent needed. MTDs may also be used as an adjunctive procedure for incomplete thrombolysis or to treat distal embolic complication of catheter-directed thrombolysis.

MTDs can be categorized into (i) mechanical thrombectomy devices that mechanically disrupt thrombus along with aspirating the debris and (ii) hydrodynamic devices that rely on aspiration as well as a Venturi effect of infused saline solution or other pharmacologic agent injected under pressure. Basic principles for use of these devices are to minimize endothelial damage and downstream embolization. Many of these catheter devices allow concurrent pulse-spray administration of a thrombolytic agent. This technology has the potential to minimize the two main drawbacks of endovascular ALI therapy: the long duration of thrombolytic infusion that is needed to establish full arterial perfusion and hemorrhagic complications.

A multicenter registry of 99 patients with limb ischemia treated with the AngioJet rheolytic thrombectomy device (Medrad) reported 70% substantial or complete revascularization (i.e., <50% residual defect) and in-hospital and 30-day mortality rates of less than 5%. Primary patency rates of 74% and 69% have been reported at 3 months and 1 year, respectively. MTD complications include hemolysis and possible renal failure secondary to release of free hemoglobin. Hemolysis and fluid overload are possible with these devices. With the AngioJet device, the manufacturer recommends that the pump should be run less than 10 minutes in a flowing blood field to prevent excessive hemolysis. Also, use of the AngioJet device close to the heart may result in bradyarrhythmias (i.e., mild bradycardia to asystole) as a result of adenosine release caused by cell lysis. The current commercially available MTDs for ALI—the AngioJet (Medrad), Jetstream (Pathway Medical, Kirkland, Washington), and Rinspirator (ev3, Plymouth, Minnesota) devices—are all plagued with large particulate debris and distal embolization.

Isolated pharmacomechanical thrombolysis may help to minimize or possibly eliminate the risk of embolization. The Trellis-6 peripheral infusion system (Covidien) uses balloons that are inflated, one proximal to the thrombus and the other distal to the thrombus. Between the balloons are infusion holes through which the thrombolytic agent is introduced, limiting systemic dispersion. Then, mechanical dispersion of the thrombolytic agent with maceration of the clot is accomplished by oscillation of the catheter by a powered sinusoidal wire. Then, the dissolved clot is aspirated through the catheter.

Well organized emboli are still problematic for most MTD devices. Use of MTDs may reduce the thrombus mass, thereby reducing the length of time of catheter-directed thrombolysis and the total dose of thrombolytic drug needed to achieve clinical success, possibly decreasing hemorrhagic complications and improving outcome. However, experience with MTDs is limited. Limited population sizes in multiple retrospective studies with different definitions of success and outcomes limits critical analysis. Comparative randomized studies are needed to determine if MTDs are faster and safer, and how effective they are compared with pharmacologic thrombolysis. A few nonrandomized studies document higher amputation-free success rates associated with initial endovascular MTD procedures, with low repeat intervention rates. MTDs may serve a role in removal of clot in patients with category IIb acute ischemia within 2 hours of presentation of symptoms. A recommendation based on current literature for use of MTDs as a stand-alone method for thrombolysis cannot be made.

## Clinical Algorithm(s)

An algorithm titled "Proposed Algorithm for Management of ALI" is provided in the original guideline document.

# Scope

## Disease/Condition(s)

Acute lower-extremity (limb) ischemia (ALI)

## Guideline Category

Diagnosis

Evaluation

Management

Treatment

## Clinical Specialty

Family Practice

Hematology

Internal Medicine

Radiology

## Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To improve the quality of percutaneous management of acute lower-extremity ischemia (ALI)

## Target Population

Patients with acute lower-extremity (limb) ischemia (ALI)

## Interventions and Practices Considered

Diagnosis/Evaluation

1. Patient selection based on clinical findings (particularly acute ischemia [Rutherford] category)
2. Medical history and symptom assessment
3. Physical examination
4. Laboratory tests including renal function, baseline hematocrit and coagulation profile, and evidence of hyperkalemia and acidosis

5. Electrocardiogram
6. Doppler examination of the limb
7. Evaluation of patients for absolute and relative contraindications to thrombolytic therapy
8. Determination of etiology of ischemia (embolic or thrombotic)

#### Management/Treatment

1. Thrombolytic agents: urokinase (UK), tissue plasminogen activators (TPAs) (alteplase, reteplase)
2. Methods of delivery of thrombolytic agents (note: intravenous administration not recommended)
3. Concomitant heparin administration
4. Laboratory monitoring of serum fibrinogen levels and hemoglobin
5. Adjunctive techniques (e.g., percutaneous mechanical thrombectomy devices [MTDs], percutaneous aspiration thrombectomy [PAT])

### Major Outcomes Considered

- Overall clinical success
- Overall technical success
- Major complications including mortality

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

An in-depth literature search was performed by using electronic medical literature databases (mainly Medline searching as far back as database allows). Search terms included *limb* or *leg*, *ischemia*, *acute*, *cold*, *thrombolysis*, *thrombectomy*, *thromboaspiration*, *clot removal* plus whatever terms came up for *Seminars in Vascular Surgery* Rutherford paper (Rutherford RB. Clinical staging of acute limb ischemia as the basis for choice of revascularization method: how and when to intervene. *Semin Vasc Surg* 2009; 22:5–9). Studies included were series with more than 25 patients for thrombolysis.

### Number of Source Documents

Not stated

### Methods Used to Assess the Quality and Strength of the Evidence

Not stated

### Rating Scheme for the Strength of the Evidence

Not applicable

### Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, complication rates, outcomes, and thresholds for prompting quality assurance reviews.

## Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a modified Delphi consensus method. For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter. In addition, for the specific purpose of this guideline document, studies with fewer than 50 patients were not included for the purpose of defining the parameters established.

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the Society of Interventional Radiology (SIR) HI-IQ System national database.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

The draft document is critically reviewed by the Standards of Practice Committee members by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the Society of Interventional Radiology (SIR) membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions are made to create the finished Standards document. Before its publication, the document is endorsed by the SIR Executive Council.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.



# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Improved quality of percutaneous management of acute lower-extremity ischemia (ALI)

## Potential Harms

### Major Complications for Thrombolysis of Acute Lower-Extremity Ischemia (ALI)

#### Pharmacologic

- Intracranial hemorrhage
- Major bleeding requiring transfusion and/or surgery
- Compartment syndrome
- Distal embolization not corrected with thrombolysis

#### Mechanical

- Distal embolization (mechanical thrombectomy/aspiration)

#### Other Adverse Effects

- Intrathrombus bolus tissue plasminogen activator (TPA) administration is associated with increased risk of hemorrhage compared with lower-dose continuous infusion.
- Mechanical thrombectomy device (MTD) complications include hemolysis and possible renal failure secondary to release of free hemoglobin.

## Contraindications

### Contraindications

Contraindications to pharmacologic thrombolytic therapy are based on medical conditions thought to increase the risk of local and remote hemorrhage.

#### Absolute Contraindications

- Active clinically significant bleeding
- Intracranial hemorrhage
- Presence/development of compartment syndrome
- Absolute contraindication to anticoagulation

#### Relative Contraindications

- Bleeding diathesis
- Disseminated intravascular coagulation
- Established cerebrovascular event (including transient ischemic attacks) within past 2 months
- Neurosurgery (intracranial, spinal), or intracranial trauma within past 3 months
- Cardiopulmonary resuscitation within past 10 days
- Major surgery, or major trauma within past 10 days
- Recent eye surgery within past 3 months
- Intracranial tumor, vascular malformation, aneurysm, or seizure disorder
- Uncontrolled hypertension (>180 mm Hg systolic or >110 mm Hg diastolic blood pressure)
- Recent internal hemorrhage, puncture of noncompressible vessel or organ biopsy

- Recent major gastrointestinal bleeding within past 10 days
- Serious allergic or other reaction to thrombolytic agent, anticoagulant, or contrast media (not controlled by steroid/antihistamine pretreatment)
- Severe thrombocytopenia
- Pregnancy and immediate postpartum status
- Severe liver dysfunction, particularly in cases with coagulopathy
- Bacterial endocarditis
- Diabetic hemorrhagic retinopathy
- Life expectancy of <1 year

## Qualifying Statements

### Qualifying Statements

The clinical practice guidelines of the Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents and Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

### IOM Domain

Effectiveness

Safety

# Identifying Information and Availability

## Bibliographic Source(s)

Patel NH, Krishnamurthy VN, Kim S, Saad WE, Ganguli S, Walker TG, Nikolic B, CIRSE and SIR Standards of Practice Committees. Quality improvement guidelines for percutaneous management of acute lower-extremity ischemia. J Vasc Interv Radiol. 2013 Jan;24(1):3-15. [119 references] [PubMed](#)

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2005 May (revised 2013 Jan)

## Guideline Developer(s)

Cardiovascular and Interventional Radiological Society of Europe - Nonprofit Organization

Society of Interventional Radiology - Medical Specialty Society

## Source(s) of Funding

Society of Interventional Radiology

## Guideline Committee

Society of Interventional Radiology Standards of Practice Committee

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## Financial Disclosures/Conflicts of Interest

N.H.P. is a paid consultant for DFine Inc, Stryker, and Promex Technology and has a royalty agreement with Promex Technology. None of the other authors have identified a conflict of interest.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Rajan DK, Patel NH, Valji K, Cardella JF, Brown DB, Brountzos EN, Clark TW, Grassi CJ, Meranze SG, Miller DL, Neithamer CD, Rholl K, Roberts A, Schwartzberg MS, Swan TT, Thorpe PE, Towbin RB, Sacks D, CIRSE and SIR Standards of Practice Committees. Quality improvement guidelines for percutaneous management of acute limb ischemia. J Vasc Interv Radiol. 2009 Jul;20(7 Suppl):S208-18. [91 references]

## Guideline Availability

Electronic copies: Available from the [Society of Interventional Radiology Web site](#) .

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

## Availability of Companion Documents

None available

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on August 19, 2011. The information was verified by the guideline developer on September 8, 2011. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins. This summary was updated by ECRI Institute on January 23, 2015.

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